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IN THE

Supreme Court of the United States

OCTOBER TERM 1974

No. 74-1443

OIL, CHEMICAL AND ATOMIC WORKERS INTERNATIONAL UNION, AFL-CIO,

and

HEALTH RESEARCH GROUP,

Petitioners,

v.

JOHN T. DUNLOP, Secretary, United States Department of Labor

and

JOHN H. STENDER, Assistant Secretary, Occupational Safety and Health Administration, United States Department of Labor

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

ALAN B. MORRISON
BERTRAM ROBERT COTTINE

Suite 700
2000 P Street, N.W.
Washington, D.C. 20036
(202) 785-3704

Attorneys for the Petitioners

ABB DUPLICATORS, INC.—1722 Eye Street, N.W.—Washington, D.C.—[illegible]

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OPINION BELOW

The opinion of the United States Court of Appeals for the Third Circuit (Appendix A, *infra*, pp. 1a-13a) is reported at 506 F.2d 385. That opinion reviewed the validity of the issuance by the Secretary of Labor (the "Secretary") of occupational health standards regulating fourteen cancer-causing chemicals. The statement of reasons applicable to all fourteen standards and a representative carcinogen standard issued by the Secretary, 29 C.F.R. §1910.93*c-p*, 39 *Fed. Reg.* 3756 (January 29, 1974), are set out in Appendix B, *infra*, pp. 14a-42a.

JURISDICTION

The judgment of the Court of Appeals was entered on December 17, 1974. (Appendix D, *infra*, p. 45a) The time for filing a petition for writ of certiorari was extended until May 16, 1975 by an order entered on March 6, 1975. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1). Original jurisdiction was invoked in the Court of Appeals under 29 U.S.C. §655(f).

QUESTION PRESENTED

Did the Court of Appeals err in testing the validity of the Secretary's omission of two vital protections from occupational health standards involving fourteen cancer-causing chemicals by asking only whether the Secretary's decision was a reasonable judgment rather than by measuring the decision against the statutory provisions which mandate these vital protections?

STATUTE INVOLVED

Sections 6(b)(5) and 6(b)(7) of the Occupational Safety and Health Act of 1970, 84 Stat. 1594, 1595-1596, 29

U.S.C. §§655(b)(5), 655(b)(7), are set out in Appendix C, *infra*, pp. 43a-44a.

STATEMENT OF THE CASE

Convinced that the human toll from workplace hazards must be effectively controlled, Congress enacted the Occupational Safety and Health Act, 29 U.S.C. §§651 *et seq.* (1970). Section 6(b)(5) of the Act specifically mandated the Secretary to set health and safety standards which ". . . most adequately assure that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure . . . for the period of his working life . . . ." 29 U.S.C. §655(b)(5).[1] To guarantee this protection, Congress concluded that there were certain safeguards which were essential to worker health and safety. One of these protections was the requirement of a specific limit on the level of the toxic material in the work environment, generally referred to as a "performance standard", *Id.* Such a standard enables the Secretary to objectively measure an employer's performance in eliminating the workplace hazard. In addition, Congress required that the standards include a system to detect and measure worker exposure to the hazard so that regular checks would be made of the workplace to measure performance against the promises made ("monitoring") 29 U.S.C. §655(b)(7). This petition seeks review

[1] The Secretary delegated his functions under the Act to the Assistant Secretary of Labor for Occupational Safety and Health, Secretary's Order #12-71. Both of these officials were respondents in the Court of Appeals and are respondents in this Court.

of (a) the failure of the Secretary to include in the standards regulating fourteen cancer-producing chemicals ("carcinogens") any performance standard whatsoever and his indefinite deferral of any monitoring requirement, and (b) the failure of the Court of Appeals to require the Secretary to amend the standards by providing for these two elements.

A. Administrative Proceedings

The governmental inquiry into the deaths and serious health hazards confronting workers exposed to these fourteen carcinogens began in May 1972 when the Secretary requested the National Institute for Occupational Safety and Health ("NIOSH")[2] to investigate the cancer hazard. NIOSH transmitted fact sheets on these carcinogens to the Secretary in July 1972 and its investigation culminated in a NIOSH request for whatever additional information the public might have. 37 *Fed. Reg.* 13285 (July 6, 1972). Since continued human exposure to these chemicals presented a grave danger, and since the Secretary took no action to regulate them, the Oil, Chemical and Atomic Workers Union ("OCAW") and the Health Research Group, requested the Secretary to issue an emergency temporary standard under section 6(c) of the Act, 29 U.S.C. §655(c). Their petition documented the cancer hazard and proposed a standard which included a performance standard and monitoring among other important protections.[3] Inspite of the urgency of the matter, no standard was promulgated until after the

[2]NIOSH is organized within the Department of Health, Education and Welfare, 29 U.S.C. §671.

[3]The Secretary noticed receipt of the petition and published the text of the standard suggested by the petitioners for public comment, 38 *Fed. Reg.* 4037, 4038-4039 (February 9, 1973).

petitioners filed a mandamus action to compel the Secretary to act on their request for an emergency temporary standard.[4] On May 3, 1973, the Secretary finally issued an emergency standard to deal ". . . with the exposure of employees to certain listed substances that are known to cause cancer." 38 *Fed. Reg.* 10929. Specifically, the Secretary found that: ". . . (1) the 14 carcinogens listed in the emergency temporary standard are toxic and physically harmful; (2) that exposure to any of the 14 substances poses a grave danger to employees; (3) that employees are presently being exposed to the substances; and (4) that the emergency temporary standard set forth below is necessary to protect employees from such exposure." *Id.*

Although the emergency standard required employers using these chemicals to institute certain work practices, it did not place a definite limit on worker exposure to the carcinogens by setting a performance standard. In omitting any limit on worker exposure above fixed levels, the Secretary violated the statutory mandate that ". . . [w]henever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired." 29 U.S.C. §655(b)(5). Moreover, the Secretary did not even require employers to measure worker exposure to these carcinogens, ignoring completely section 6(b)(7) which directs the inclusion of ". . . monitoring or measuring employee exposure . . . as may be necessary for the protection of employees . . ." in these standards. 29 U.S.C. §655(b)(7). Instead, the Secretary merely required employers to report ". . . the type of

[4] *Oil, Chemical & Atomic Workers Int'l Union v. Brennan*, Civil Action No. 730-73 (D.D.C., filed April 17, 1973).

monitoring system [if any] that has been instituted . . ." 38 *Fed. Reg.* 10930 (May 3, 1973), a tactic he also employed with regard to the medical surveillance requirement.[5] In fact, his statutorily required statement of reasons[6] never mentioned any of the mandated protections contained in the Act, let alone explained their omission from the emergency standard.

Petitions for review were filed in the Third Circuit by industry representatives, who challenged the inclusion of two chemicals — EI and DCB — on the list of carcinogens,[7] and by petitioners here, who challenged the adequacy of the protection afforded by the standard in the face of the Secretary's finding that the chemicals posed a grave danger to worker health. Although petitioners urged consideration of the Secretary's failure to follow the statutory mandates of sections 6(b)(5) and 6(b)(7), the Court of Appeals addressed itself exclusively to the industry claim that two of the chemicals were improperly found to be carcinogens, *Dry Color Mfrs. Ass'n v. Dep't of Labor*, 486 F.2d 98 (3d Cir. 1973). The Court set aside those findings because of an inadequate statement of reasons, but declined to address the issues of monitoring, medical surveillance, and a performance standard argued by petitioners. *Id.* at 108.

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[5] Section 6(b)(7) of the Act, 29 U.S.C. §655(b)(7), requires the inclusion of ". . . medical examinations and other tests . . . to most effectively determine whether the health of such [exposed] employees is adversely affected . . . ."

[6] Section 6(e), 29 U.S.C. §655(e).

[7] EI is the acronym for ethyleneimine and DCB the acronym for 3,3'-dichlorobenzidene.

The Act requires the Secretary to replace an emergency temporary standard with a permanent standard within six months. 29 U.S.C. §655(c)(3). In order to obtain expert advice on this new standard, the Secretary convened an advisory committee under section 6(b)(1), 29 U.S.C. § 655(b)(1).[8] But the advisory committee refused to ratify the inadequacies of the emergency standard with the Secretary's deviations from the requirements of the Act. Instead, it recommended a performance standard of "no measurable exposure or contact" to the cancer-producing chemicals. 38 *Fed. Reg.* 24377 (September 7, 1973). The committee also stressed the need for monitoring to detect the presence of these carcinogens in the workplace, and advised the Secretary to include sufficient medical surveillance to determine the adverse effects of continued human exposure to each of these carcinogens. *Id.*

The permanent standard, which was not promulgated until January 29, 1974, almost three months after the statutory deadline, was premised on the conclusion that ". . . a safe level of human exposure to any of the 14 carcinogens cannot be established by the application of present knowledge . . . ." (App. B, p. 20a). However, the Secretary failed to implement this finding by requiring a performance standard, monitoring, and adequate medical surveillance which are mandated by the Act. On the performance standard issue, the Secretary restricted his consideration to the "no detectable level" standard proposed by petitioners and later recommended by the advisory committee (*Id.* at 20a-21a). He never addressed his general obligation to set a performance standard,

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[8] The advisory committee met for eighteen days and considered evidence from government agencies and other experts, including extensive presentations from industry.

whether at the zero level or some other level — a failure which is exemplified by the absence of any discussion of the section 6(b)(5) preference, if not a requirement, for performance standards.

Having failed to establish a definite limit on worker exposure, the Secretary further eroded worker protection by omitting any requirement that employers monitor the workplace to detect the amount of the carcinogen to which workers are exposed. In a brief two sentences the Secretary dismissed his statutory responsibility to prescribe monitoring, and merely referred the development of a monitoring requirement to NIOSH, an agency over which he has no control, 29 U.S.C. §§671(a), 671(b), and imposed no time limits on the receipt of NIOSH's work.[9]

Finally, having failed to insure adequate control of worker exposure by refusing to set a performance standard, and having refused to provide monitoring to determine the extent of worker exposure, the Secretary issued totally inadequate requirements for medical surveillance. Instead of prescribing specific tests to detect particular forms of cancer caused by different carcinogens, the Secretary left the selection of the techniques entirely to the employers. In spite of the Secretary's admission that specific medical surveillance was necessitated by the long latency period

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[9] In turn, NIOSH signed an interagency agreement on May 20, 1974, with the former Atomic Energy Commission to develop monitoring techniques. This agreement is not scheduled for completion until September 30, 1976 — a full two and a half years after the issuance of the permanent standards. U.S. Dep't of Health, Education & Welfare, Nat'l Inst. for Occupational Safety & Health, *Interagency Agreement #NIOSH-IA-74-35* at 7 (1974).

between a worker's first exposure to the carcinogen and the first appearance of cancer (App. B, p. 20a), the advisory committee recommendations were ignored entirely. Once again, the statement of reasons reflects no concern for the statutory obligation to specify the contents of the required medical examinations and diagnostic tests.

In sum, while the finding by the Secretary that the fourteen chemicals presented grave dangers of inducing cancer suggested the need for stringent measures to protect the workers, the Secretary's standards fell far short of the minimum requirement under the Act that the standards ". . . most adequately assure that no employee will suffer material impairment of health . . ." as a result of exposure to these carcinogens. Section 6(b)(5), 29 U.S.C. §655(b)(5).

B. The Decision of the Court of Appeals

Once again petitions for review were filed in the Third Circuit by the employers who used chemicals found to be carcinogens. This time, however, there were challenges not only to EI and DCB, but also to CCME and MOCA.[10] Petitioners once again filed for review under section 6(f) of the Act, 29 U.S.C. §655(f), raising substantially the same objections to the permanent standard that they had presented to the Third Circuit on the emergency standard and to the Secretary and the advisory committee during the proceedings on the permanent standard. At the request of the employers who utilized EI, that petition for

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[10] CMME is the acronym for methyl chloromethyl ether and MOCA® is the registered trade mark for 4,4'-methylene bis (2-chloroaniline).

review was severed from the remainder of the case, and an expedited schedule was ordered. Before the argument was held on the remaining cases, the Court of Appeals affirmed the determination of the Secretary that EI was a carcinogen, but reversed the part of the standard relating to its use in laboratories and remanded that matter for further proceedings. *Synthetic Organic Chemical Mfrs. Ass'n v. Brennan*, 503 F.2d 1155 (3d Cir. 1974), *cert. denied*, ____ U.S. ____, 95 S.Ct. 1396 (1975).

Thereafter, on December 17, 1974, a different panel of the Third Circuit affirmed the Secretary's determination that the other three chemicals whose carcinogenicity was being contested also presented a significant risk of cancer to humans exposed to them. (App. A, pp. 3a-5a). However, the Court concluded that the Secretary had not followed the statutory procedures and timetable for utilization of advisory committees and hence the standard dealing with MOCA — the only chemical as to which the objection was raised — was ". . . remanded to the Secretary for compliance with the statutory mandate." (App. A, p. 5a).

The Court then turned to its review of the portions of the standards which petitioners claimed to be insufficient to protect exposed workers and to be in violation of various provisions of the Act. Initially it considered the Secretary's failure to prescribe a performance standard. Like the Secretary, it made the fundamental error of restricting its examination to whether a particular performance standard — one requiring "no measurable exposure" — was appropriate, rather than deciding whether the Secretary erred in omitting any performance standard, be it at zero tolerance or some other level of exposure. Having so limited the issue, and without reference to the contrary recommendation of the advisory committee, the Court concluded that

the Secretary's decision was ". . . a reasonable exercise of judgment in the policy-making sphere." (App. A, p. 10a). In its brief discussion of the question, section 6(b)(5), which directs the Secretary to utilize a performance standard, was neither cited nor discussed by the Court.[11]

The next deficiency in the standard was also brushed aside by the Court quite quickly. Although the standard lacked any monitoring to detect worker exposure to these carcinogens, the Court sustained the Secretary's decision to request another agency to develop methods for determining amounts of carcinogens in the workplace (App. A, p. 11a). Unable to find any explanation for this buck-passing in the statement of reasons, the Court explained it by restating what the Secretary had done: ". . . in effect the Secretary has deferred implementation of monitoring requirements pending further development of methods for doing so . . . ." (*Id.* at 12a). The Court ignored entirely the monitoring recommendations of the advisory committee,[12] the Secretary's own compilation of available monitoring techniques,[13] and the broad statutory

[11] The Act also directs the Secretary to consider ". . . experience gained under this and other health and safety laws . . . ." 29 U.S.C. §655(b)(5). Performance standards known as "threshold limit values" had previously been set for all toxic substances regulated by the Secretary, 29 C.F.R. §§1910.93, Tables G-1, G-2 & G-3, 1910.93*a* (1974). Neither the Secretary nor the Court explained why this experience did not support the use of a performance standard in regulating these fourteen carcinogens.

[12] 38 *Fed. Reg.* 24377 (September 7, 1973).

[13] Occupational Safety and Health Administration, U.S. Dep't of Labor, *Supplement to Final Environmental Impact Statement on Proposed Regulation: Handling of Certain Carcinogens* 63-66 & Tables I-III (filed December 3, 1973).

authorization to act on the basis of the "best available evidence" and the "latest available scientific data in the field," 29 U.S.C. §655(b)(5). And, most importantly, the Court again failed to consider the governing statutory mandate to provide ". . . monitoring or measuring exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees . . . ." 29 U.S.C. §655(b)(7).

Finally, the Court confronted the inadequate medical surveillance required by the standard. This time, however, the Court was not satisfied with the Secretary's failure ". . . to explain the lack of specific requirements making the medical examinations effective . . ." (App. A, p. 13a), and this dissatisfaction led it to compare the standard to the advisory committee recommendations. (*Id.* at 12a). It also noted but did not comment or rely on the requirement of section 6(b)(7), which directs the Secretary ". . . to prescribe the type and frequency of medical examinations . . . to most effectively determine whether the health of such employees is adversely affected by such exposure." (*Id.*) Based on this analysis, it found the standard to be inadequate. The Court remanded because "[t]he Secretary gave no reasons for ignoring this recommendation of the advisory committee, nor did he indicate, as he did in connection with monitoring devices, that further information was needed." (*Id.*) But even in this action, reversing the Secretary's determinations concerning medical surveillance, the Court of Appeals fell into the same error as on the other two points: it judged the standard by whether the Secretary's action appeared reasonable and not by whether it was within the statutory guidelines set forth in sections 6(b)(5) and 6(b)(7) of the Act.

REASONS FOR GRANTING THE WRIT

A. The Decision Below Violates the Duty of Appellate Courts to Review Questions of Law and Thus Seriously Compromises the Basic Protections Afforded Workers by the Act.

The failure of past efforts to eliminate serious workplace hazards prompted Congress to pass the Occupational Safety and Health Act of 1970. In it Congress sought to eradicate a nation-wide epidemic which caused 14,500 deaths and disabled 2.5 million workers each year. S. Rep. No. 91-1282, 91st Cong., 2d Sess. 2 (1970) (hereafter "Senate Report"). The objective of the Act is ". . . to reduce the number and severity of work-related injuries and illnesses, which despite current efforts of employers and government, are resulting in ever-increasing human misery and economic loss," Senate Report at 1. It intended to do this by providing every working man and woman a safe and healthful workplace. 29 U.S.C. §651(b).

Congress was also keenly aware of the 390,000 new cases of occupational disease each year. Senate Report at 2. The problems resulting from past inaction in regulating health hazards are compounded by the fact that ". . . every 20 minutes a new and potentially toxic chemical is introduced into industry . . ." *Id.* Furthermore, Congress found that over 65% of industrial workers were exposed to harmful physical agents or toxic materials. H.R. Rep. No. 91-1291, 91st Cong., 2d Sess. 15 (1970). Among these were the lung carcinogen asbestos and the bladder carcinogen beta-naphtylamine, Senate Report at 3-4, the latter being one of the fourteen carcinogens involved in these standards.

This serious public health problem could have been tackled by simply delegating broad rulemaking authority to the Secretary as Congress had done in the past. *E.g.*, Walsh-Healy Public Contracts Act, 38 U.S.C. §§35, 38. The House bill would have copied this former approach and would have left the Secretary unlimited discretion in regulating workplace hazards. H.R. 16785, 91st Cong., 2d Sess. §6 (1970) (engrossed bill).[14] However, the Senate insisted that the Secretary be directed to promulgate standards for toxic materials which ". . . most adequately assure . . . that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life . . ." S. 2193, 91st Cong., 2d Sess. §6(b) (1970). In addition, the Senate did not leave the Secretary free to formulate the contents of a standard without Congressional guidelines. The non-impairment rule was strengthened by directions to include specific provisions in each standard. Thus, section 6(b)(5) and 6(b)(7) required a performance standard, monitoring, and medical surveillance, as well as appropriate protective equipment, labels, and warnings. In each case the Senate's detailed directions were adopted in preference to the House bill which contained no comparable, specific provisions except for labels and warnings. H.R. Rep. No. 91-1795, 91st Cong., 2d Sess. 35 (1970). The result was a statute which contained not only a general admonition to the Secretary to protect the health of workers,

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[14] Senate Comm. on Labor & Public Welfare, *Legislative History of the Occupational Safety & Health Act of 1970*, 92d Cong., 1st Sess. 1094-1095 (1971).

but the equivalent of a check list of techniques which he was to utilize in most, if not all, the cases.[15]

Instead of reviewing the Secretary's action in terms of the controlling statutory mandates, the Court of Appeals merely looked to the statement of reasons. It then concluded that the Secretary's omission of a performance standard was a ". . . reasonable exercise of his judgment in the policy-making sphere" (App. A, p. 10a), and that the omission of a monitoring provision was a "pragmatic decision" (*Id.* at 12a). In neglecting to measure these standards in terms of their statutory framework, the court below significantly failed to perform the function assigned to it by Congress.

This Court has consistently maintained that the final authority to interpret Congressional enactments is vested in the judiciary, *United States v. American Trucking Ass'n*, 310 U.S. 534 (1940); *Marbury v. Madison*, 5 U.S. (1 Cranch) 137 (1803), even in those instances in which Congress has delegated legislative or adjudicatory functions to an administrative agency, *FTC v. Texaco, Inc.*, 393 U.S. 223 (1968); *National Broadcasting Co. v. United States*, 319 U.S. 190 (1943). This is particularly true

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[15] Each of these provisions contains such phrases as "whenever practicable" or "where appropriate" thus indicating that all of these standards, which cover safety hazards such as physical agents as well as these chemical carcinogens, need not contain all these provisions in every case. Nonetheless, a fair reading of these requirements indicates that inclusion is the general rule. In this case, the Secretary did not even explain his reasons for omitting these provisions. Yet, the Secretary is obligated to state the significant issues which have been faced and then articulate the rationale underlying their resolution, *Associated Industries of New York State v. U.S. Dep't of Labor*, 487 F.2d 342, 353-354 (2d Cir. 1974).

where statutory limitations are involved, *e.g., FMC Seatrain Lines, Inc.*, 411 U.S. 726 (1973), or where administrative action has been mandated by the statute, *Train v. City of New York*, ____ U.S. ____, 95 S.Ct. 839 (1975); *Train v. Campaign Clean Water, Inc.*, ____ U.S. ____, 95 S.Ct. 847 (1975). Where there is an administrative interpretation of statutory authority, the courts are ". . . not obliged to stand aside and rubber stamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the Congressional policy underlying a statute . . ." *N.L.R.B. v. Brown*, 380 U.S. 278, 291 (1965); *Volkswagenwerk Aktiengesellschaft v. FMC*, 390 U.S. 261, 272 (1968); *FMC v. Seatrain Line, Inc., supra*, at 746. Moreover, "[t]he deference owed to an expert tribunal cannot be allowed to slip into judicial inertia . . ." *American Ship Building Co. v. N.L.R.B.*, 380 U.S. 300, 388 (1965).

The reviewing court has an affirmative obligation to review administrative action regardless of the Secretary's failure, as in this case, to analyze his obligations in terms of the statutory mandate. The Court must delineate the scope of the Secretary's authority and discretion, and identify the range of choices left to the administrator by Congress. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 415-416 (1971). Where there is little choice left to the administrator, the Court must carefully review compliance with the statutory requirements. *Id.* Judicial review thus necessitates a determination that the administrator's action conforms with the statutory mandates, *Train v. City of New York, supra*, and is consistent with the Congressional purpose, *Morton v. Ruiz*, 415 U.S. 199 (1974). Finally, the reviewing court must interpret the statute as mandatory when to do otherwise would

seriously impair the interests to be protected, *Escoe v. Zerbst*, 295 U.S. 490, 494 (1935).

Although section 6(b) dictates a limited range of choices for monitoring and a performance standard, the Court of Appeals has obliterated those limitations by failing to examine the statute at all. Instead, by concentrating its exclusive attention on the statement of reasons, it has abdicated the role assigned by Congress in reviewing the legal issues arising from the Secretary's interpretation, or more accurately, his non-interpretation, of the Act. The gravity of the abidcation of the Third Circuit is compounded here because these chemicals pose a cancer hazard to workers, and, as the Secretary himself acknowledged, there is no known safe level of exposure to these carcinogens (App. B, p. 20a).

The refusal of the Court of Appeals to at least insist on an explanation from the Secretary for not including these provisions is even less understandable in view of the wide spread practice of including performance requirements and monitoring in other standards issued under the Act, as the Secretary's own advisory committee recommended. For instance, the Secretary adopted as "established federal standards" under section 6(a) of the Act, 29 U.S.C. §655(a), nearly 400 performance standards for a variety of toxic substances that had originally been issued under the Walsh-Healy Act. 29 C.F.R. §1910.93, Tables G-1, G-2, & G-3 (1974). And in the first carcinogen standard promulgated under section 6(b), the Secretary included not only a performance standard, but also extensive monitoring provisions. 29 C.F.R. §1910.93*a*(b), (f) (1974) (asbestos).[16]

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16 Subsequent to the issuance of the standards at issue here, the Secretary promulgated both emergency and permanent standards

(continued)

Because the court below failed to discharge its duty to review these standards in light of the requirements imposed by Congress, this Court should grant the writ and direct the Court of Appeals and the Secretary to consider the propriety of the standards under the tests established by the Act. In this way the health of the 10,000 employees affected by these chemicals will be protected in the manner provided by Congress, and the courts of appeals will be given specific guidance on the performance of their functions under the Act.[17]

B. This Court Should Settle A Critical Question Regarding Judicial Review of Occupational Safety and Health Standards On Which the Circuits Appear to Be in Conflict.

Three other circuits have been called upon to review the Secretary's actions in terms of the statutory requirements, and each has directly compared the action to the terms of the Act. In *Florida Peach Growers Ass'n v. U.S. Dep't of Labor*, 489 F.2d 120 (5th Cir. 1974), the Court enforced the section 6(c)(1) requirement that a "grave

16 (continued)
for vinyl chloride which contain performance standards and a monitoring requirement. 29 C.F.R. §1910.93*q*(b), (c), 39 *Fed. Reg.* 12342 (April 15, 1974); 29 C.F.R. §1910.93*q*(c), (d), 39 *Fed. Reg.* 35890 (October 4, 1974).

17 The petition for certiorari denied by this Court with respect to the determination that EI was a carcinogen sought to question the approach of the Court of Appeals in applying the substantial evidence test to factual findings under section 6(f), 29 U.S.C. §655(f). Thus, that petition (No. 74-789) presented a very different type of issue from the one presented here.

danger" must support the issuance of an emergency temporary standard and required the Secretary to satisfy this statutory prerequisite. In another case involving the safety net standard, the Seventh Circuit directly applied the committee membership requirements of section 7(b) to the construction advisory committee even though it considered the petitioners' claims "frivolous." *National Roofing Contractors Ass'n v. Brennan*, 495 F.2d 1294 (1974), *cert. denied*, ____ U.S. ____, 95 S.Ct. 775 (1975). Significant issues were raised regarding the adequacy of the asbestos standard in another case, and the District of Columbia Circuit analyzed each in terms of the controlling statutory language. *Industrial Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467 (1974). And where it found that the Secretary failed to meet the requirements of section 8(c)(1) for the retention of monitoring records, that Court remanded the recordkeeping provisions to the Secretary. *Id.* at 485, 487-488. The Court also emphasized that the reviewing court must closely examine the Secretary's action in relation to the relevant concerns of the Act, *id.* at 488, and that it must determine whether the agency had performed in accordance with Congressional purposes. *Id.* at 475. Finally in *Associated Industries of New York State v. U.S. Dep't of Labor*, 487 F.2d 342, 353-354 (2d Cir. 1973), Judge Friendly followed the same basic approach in reviewing the lavatories standard.

Although the Third Circuit in two earlier decisions,[18] and in the part of this decision dealing with the timing of the proposed permanent standard on MOCA (App. A, pp. 5a-9a), reversed decisions of the Secretary, it did so on procedural

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[18] *Dry Color Mfrs. Ass'n v. Dep't of Labor, supra; Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, supra.*

matters that could be readily cured upon remand. However, when the Court came to the substantive mandates for worker protection, it ignored both the controlling statutory mandates and its past precedents enforcing procedural mandates. Indeed, even its reversal on the issue of medical surveillance was based almost entirely on the irrationality of the Secretary's action and not on the dictates of the Act.

C. This Court Should Settle A Critical Question of Statutory Construction Involved In the Administration and Enforcement of the Act.

Worker protections meeting the basic statutory mandates will be a central issue in setting all future health standards under the Act. The fourteen standards involved in this petition are the forerunners of hundreds of other standards which will be necessary to control workplace hazards. The most recent NIOSH *Toxic Substances List* includes 13,000 chemicals which have demonstrated toxic effects,[19] and new chemicals are constantly being introduced into the marketplace. Senate Report at 2.

Formal recommendations for 20 new standards ("criteria documents") have been transmitted to the Secretary from NIOSH and are awaiting standard-setting action, with an estimated 18.5 million workers who must confront these serious health hazards.[20] Another 31 criteria documents

[19] Nat'l Inst. for Occupational Safety & Health, U.S. Dep't of Health, Educ. & Welfare, *The Toxic Substances List — 1974 Edition* vii.

[20] Nat'l Inst. for Occupational Safety & Health, U.S. Dep't of Health, Educ. & Welfare, *Criteria for Recommended Standards on Occupational Exposure to Ammonia, Inorganic Arsenic, Benzene,*

(continued)

are expected before the end of fiscal year 1976,[21] and NIOSH has recently begun an inquiry into the dangers of 29 other chemical substances.[22] However, planned government projects will not be the only source of new standards in the future, as evidenced by the unexpected disclosure of new hazards for both vinyl chloride[23] and arsenic.[24]

Every new standard will necessarily involve the statutory requirements for a performance standard, monitoring, medical surveillance, and the other mandates of section 6(b)(7). Furthermore, in the next two years almost 400 "established federal standards" promulgated in 1971[25] will be supplemented with the monitoring, medical surveillance, and other requirements under section 6(b)(7) that they now lack.[26]

20 (continued)
Beryllium, Carbon Monoxide, Chloroform, Chromic Acid, Coke Oven Emissions, Cotton Dust, Crystalline Silica, Hot Environments, Inorganic Lead, Inorganic Mercury, Noise, Sulfur Dioxide, Sulfuric Acid, Toluene, Toluene Diisocyanate, Trichloroethylene, & Ultraviolent Radiation (1972-1975).

21 3 CCH Employment Safety & Health Guide ¶9545 (1975).

22 39 *Fed. Reg.* 44792 (December 27, 1974); 40 *Fed. Reg.* 7960 (February 24, 1975); 40 *Fed. Reg.* 13231 (March 25, 1975).

23 39 *Fed. Reg.* 3874 (January 30, 1974) (fact-finding hearing); 39 *Fed. Reg.* 12342 (April 15, 1974) (emergency temporary standard).

24 39 *Fed. Reg.* 31644 (August 30, 1974) (fact-finding hearing); 40 *Fed. Reg.* 3392 (January 21, 1975) (proposed permanent standard).

25 36 *Fed. Reg.* 10466, 10503-10506 (May 29, 1971).

26 Notices of proposed rulemaking appear at 39 *Fed. Reg.* 33843 (June 20, 1974); 40 *Fed. Reg.* 4019 (January 27, 1975); 40 *Fed. Reg.* 4930 (February 3, 1975); 40 *Fed. Reg.* 11890 (March 14, 1975); 40 *Fed. Reg.* 17654 (April 21, 1975); 40 *Fed. Reg.* 20201 (May 8, 1975).

The issues raised in this petition regarding judicial review and the worker protections required by the Act, will have universal application to this enormous standard-setting activity. Resolution of these statutory issues by this Court will assist the Secretary in meeting his statutory obligations and guide the courts of appeals in reviewing these standards.

Finally, occupational health and safety standards are the primary enforcement method under the Act, *Brennan v. Occupational Safety & Health Review Comm'n*, 491 F.2d 1340, 1343 (2d Cir. 1974). Where a standard lacks protective provisions such as monitoring or medical surveillance, compulsory enforcement of these protections under sections 9 and 10 of the Act will be extremely difficult. *See generally, American Smelting & Refining Co. v. Occupational Safety & Health Review Comm'n*, 501 F.2d 504 (8th Cir. 1974). Even employer efforts at voluntary compliance are seriously compromised when the standard lacks any specific guidance on worker protections.

The cancer hazard posed by these fourteen chemicals immediately affects ten thousand workers. However, the necessary protection of the 57 million workers covered by the Act is directly dependent on the promulgation and enforcement of standards which afford the complete protection mandated by Congress. This Court, by reviewing the decision below and directing the Secretary and the courts of appeals to comply with the Act, can significantly advance the effectiveness of the worker protection provided by Congress and give badly needed guidance to all concerned and thereby avoid unnecessary litigation.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

ALAN B. MORRISON
BERTRAM ROBERT COTTINE

Suite 700
2000 P Street, N.W.
Washington, D.C, 20036
(202) 785-3704

Attorneys for the Petitioners

May 16, 1975

APPENDIX A

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 74-1129
No. 74-1149
No. 74-1268

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, ET AL.,
Petitioners in No. 74-1129

v.

PETER J. BRENNAN, SECRETARY, DEPARTMENT OF LABOR, ET AL.,
Respondents.

OIL, CHEMICAL & ATOMIC WORKERS INTERNATIONAL UNION, AFL-CIO, ET AL.,
Petitioners in No. 74-1149

v.

PETER J. BRENNAN, SECRETARY, DEPARTMENT OF LABOR, ET AL.,
Respondents.

POLYURETHANE MANUFACTURERS ASSOCIATION,
Petitioner in No. 74-1268

v.

DEPARTMENT OF LABOR, ET AL.,
Respondents

ON PETITION FOR REVIEW OF ACTION OF THE ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH

Argued October 21, 1974

Before HASTIE, GIBBONS and WEIS, *Circuit Judges.*

Robert C. Barnard, Esq.
Donald L. Morgan, Esq.
Charles F. Lettow, Esq.
Eric Schwartz, Esq.
Washington, D.C. 20036
Attorneys for Petitioners in No. 74-1129

Bertram Robert Cottine, Esq.
Alan B. Morrison, Esq.
Suite 700
2000 P Street, N.W.
Washington, D.C. 20036
Attorneys for Petitioners in No. 74-1149

Arvid A. Sather, Esq.
25 West Main Street
Madison, WI 53703
Attorney for Petitioner in No. 74-1268

OF COUNSEL:

Cleary, Gottlieb, Steen & Hamilton
1250 Connecticut Avenue, N.W.
Washington, D.C. 20036

OF COUNSEL:

William J. Kilberg, Esq.
Solicitor of Labor

Benjamin W. Mintz, Esq.
Associate Solicitor for Occupational Safety & Health

Michael H. Levin, Esq.
Counsel for Appellate Litigation

Steven F. Witt, Esq.

Carla A. Hills, Esq.
Assistant Attorney General

Stephen F. Eilperin, Esq.
Michael H. Stein, Esq.
Department of Justice
Washington, D.C. 20530
Attorneys for Respondents

OPINION OF THE COURT

(Filed December 17, 1974)

WEIS, *Circuit Judge.*

The important subject of OSHA's regulations on the usage of a group of chemicals labeled as carcinogens occupies us once again. Although most of the standards are sustained, those as to laboratory practices and medical examinations of employees must be remanded. We also find validity in the objections by one of the appellants that the Secretary of Labor erred in not publishing a proposed regulation after receiving the report from his advisory committee.

These are companion cases to *Synthetic Organic Chemicals Manufacturers Association v. Brennan,* — F.2d — (No. 74-1129 3d Cir. Aug. 26, 1974), consisting of appeals from occupational health standards promulgated by the Secretary of Labor. These permanent regulations were issued on January 29, 1974, regulating, *inter alia,* the exposure of employees to fourteen chemicals found to be carcinogenic. 29 C.F.R. § 1910.93c-p.

Appeals to this court were filed on behalf of employers who utilized four of the chemicals—EI, CMME, DCB and MOCA. Another appeal was filed by the Oil Chemical and Atomic Workers Union from the standards applicable to all fourteen substances. The appeal as it pertained to Ethyleneimine (EI) was severed, and we held in the prior opinion that the Secretary had made sustainable determinations as to the chemical's carcinogenicity and proper standards for industrial usage. We concluded, however, that proper notice had not been given before promulgating regulations for the use of EI in the laboratory and remanded on that point. Our conclusions as to the legal issues presented by the earlier case likewise apply to the appeals now under consideration and we need not repeat what was said in our prior opinion.

The contentions made here with respect to 3, 3′-dichlorobenzidine (DCB) by employers who utilize it are similar to those raised in connection with EI—that is, the data derived from tests revealing carcinogenicity in animals were not properly extrapolated to human susceptibility. Nothing in the record permits a differentiation here from our earlier decision on EI, and we do not make one. While the scientific data varies, of course, the same legal principle applies and, accordingly, the petitioners' contention must fail.

The thrust of the opposition to the standard regulating chloromethyl methyl ether (CMME) is aimed at certain studies relied upon by the Secretary. The employers contest the validity of the Van Duuren studies[1] by questioning whether pure CMME was tested or whether, as usually occurs, the substance was contaminated to form bis chloromethyl ether (BCME).[2] Again, the issue is the same as that in the EI appeal, and again in this case the Secretary's determination finds adequate support in the record.

Polyurethane Manufacturers Association (PMA), the employers' association concerned with the use of 4,4′ methylene bis (2-chloroaniline) (MOCA)[3] in various manufacturing processes, presses the same arguments as to carcinogenicity that are advanced for DCB and CMME. Of necessity, the same criteria of review is applied to this chemical as the others in question. The Secretary's deter-

1. Van Duuren studied the properties of BCME and CMME and, in 1968, produced the first evidence for the carcinogenicity of these halo-ethers. His experiments employing both skin applications and subcutaneous injections led to the conclusion that, in the presence of certain other re-agents, and under some circumstances acting alone, CMME and BCME caused lesions in animal subjects. In each instance, Van Duuren verified the purity of the CMME used through I.R. and GLC analysis, showing no BCME content.

2. BCME is a potent chemical which industry concedes is carcinogenic. It appears that at the present time production of pure CMME is not commercially feasible. In industrial usages, it rapidly decomposes in air and aqueous solutions to form BCME and, therefore, there is no widespread usage of pure CMME now.

3. MOCA is the trade name utilized by duPont, although the same chemical is used by other industrial chemical concerns. We use the MOCA trade name because of its simplicity, but it should be understood that we are referring to the chemical, 4,4′ methylene bis (2-chloroaniline).

mination is supported by the record and therefore must be sustained.

PMA, however, raises one additional contention not presented in the other appeals. It challenges the procedures followed by the Secretary in promulgating the permanent standards for the industrial use of MOCA. This contention has merit and requires that the case be remanded to the Secretary for compliance with the statutory mandate.

MOCA was subject to the same emergency standard that was issued by the Secretary for the other thirteen chemicals on May 3, 1973 although PMA apparently did not become aware that MOCA was to be included in the group until the emergency standard was published. Thereafter, the Secretary instituted procedures to enact a permanent standard. According to 29 U.S.C. § 655(c)(2) and (3), once an emergency temporary standard is enacted, it is effective until superseded by a permanent standard fashioned in accordance with the procedures prescribed in § 655(b). The emergency standard serves as a proposed rule for that proceeding and the permanent standard must be enacted within six months. The legislative history emphasizes that "upon publication of such an emergency temporary standard, the Secretary must begin a regular standard setting procedure." 1970 *United States Code Congressional and Administrative News,* P. 5184.

We now turn to the requirements of § 655(b). That section provides that the Secretary may request the recommendations of an advisory committee to which he may submit his own proposals as well as pertinent factual and research data. The committee then submits its recommendations to the Secretary within a specified time. Paragraph (2) provides that the Secretary shall publish a proposed rule and that interested parties be given the opportunity to submit written data, comments or objections to the proposal within thirty days. If an advisory committee has been appointed, the Secretary is to publish the

proposed rule within sixty days after the submission of the committee's recommendations. Paragraph (3) provides that, if objections are filed to the proposed rule and a hearing is requested, notice of the hearing shall be given within thirty days of the last date for filing objections.

With these guidelines in mind, it is appropriate to review the chronology of the proceedings here:

May 3, 1973	—The emergency temporary standard was issued.
June 19, 1973	—The Secretary announced the formation of an advisory committee.
July 16, 1973	—The Assistant Secretary of Labor published a notice of "Commencement of rule-making proceeding," stating that the emergency standard of May 3, 1973 was proposed to be made permanent.
July 27, 1973	—The Assistant Secretary published a revision of the emergency temporary standard.
August 16, 1973	—An amended notice of proposed rule making was published to reflect the revision.
August 27, 1973	—The advisory committee submitted its recommendation to the Secretary.
September 7, 1973	—The committee's recommendations were published.
September 11-14, 1973 [4]	—Public hearings were held. Additional comments were received until September 28, 1973.

4. On September 6, 1973, PMA sent a telegram to the Assistant Secretary of Labor urging that the hearing set for September 11 be cancelled and requested that a proposed rule be published pursuant to §655(b)(2) together with an allowance of thirty days to file comments.

January 29, 1974 —The permanent standard was published as to MOCA, with separate regulations for the thirteen other substances.

The procedures followed here did not comply with § 655(b). The proposed rule was published before the advisory committee had submitted its report. Consequently, the parties were not given adequate time to submit comments or to prepare for the hearing after the committee's work was completed. Had § 655(b) been observed, under the most expeditious of circumstances, the hearing could not have been held earlier than thirty days after the advisory committee had submitted its report to the Secretary.[5]

The Secretary contends that this timetable does not apply when an emergency standard has been issued since § 655(c)(3) states that the emergency standard shall serve as a proposed rule for the paragraph (b) proceeding. If no advisory committee is appointed, paragraphs (b) and (c)(3) are consistent but when an advisory committee does function, there is a conflict between the two statutory provisions. It is our conclusion that paragraph (b) must prevail. As we said in *Dry Color Manufacturers' Association v. Department of Labor*, 486 F.2d 98, 104-105 n.9a (3d Cir. 1973):

> "The courts should not permit temporary emergency standards to be used as a technique for avoiding the procedural safeguards of public comment and hearings required by subsection 6(b). Especially where the effects of a substance are in sharp dispute, the promulgation of standards under subsection 6(b) is preferable since the procedure for permanent standards is specifically designed to bring out the relevant facts."

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5. This schedule assumes that the Secretary published the rule on the same day that he received the recommendations of the advisory committee. Obviously, if he is to give any consideration to the advisory committee report, the period must be longer. In the cases at bar, only four days elapsed between the dates of publication and hearing.

While that comment was made in another context, its underlying philosophy is pertinent.

If we were to hold that paragraph (b) does not apply, then the purpose of convening an advisory committee would be subverted. A rule which the committee was to assist in formulating would have already been published and the committee's function would be reduced to merely preparing comments to a proposal. This is not compliance with the statutory mandate that the committee shall submit its recommendations "regarding the rule to be promulgated." Congress did not intend a mere post facto role for the advisory committee because it provided that a proposed rule must be published within sixty days after submission of the committee's recommendation. § 655(b)(2).

We are not critical of the Secretary's decision to utilize an advisory committee in this instance. To the contrary, in view of the complexity of the problems, that procedure is highly desirable. *See* 1 Davis, *Administrative Law Treatise* § 6.03. However, the value of notice and comment from interested parties in a hearing for rule making was not realized in this case. As an example, the advisory committee was instructed that only one set of standards would be promulgated for all fourteen chemicals, despite the substantial differences in their properties and their industrial and laboratory uses.[6] After the public hearings had been concluded, however, the Secretary issued separate standards for each chemical.[7] Had the proposed rule recited the separate standards, the presentation of pertinent objections, comments and data would have made the public hearings far more valuable to all concerned.[8] Since the

6. Some of the committee members objected to this directive and the Secretary recognized that there was some merit to their position by publishing a revision of the emergency temporary standard on July 27, 1973. 38 Fed. Reg. 20074 (1973). However, this revision did little to solve the problem and the instructions to the committee remained unchanged.

7. Much of the language, however, in the separate standards is merely duplication of that governing all of the other chemicals.

8. PMA, for example, says that the revision of July 27, 1973 permitted it to utilize open vessel processes. However, the report of the advisory com-

procedural requirements of the statute were not observed, the standards relating to MOCA must be remanded to the Secretary for appropriate action to correct the defects.

The Oil Chemical and Atomic Workers Union (OCAW) and the Health Research Group have appealed from the standards established for each of the fourteen chemicals. These petitioners assert that the standards are deficient because:

1. they fail to include a performance standard mandating no measurable exposure to any of the chemical substances;
2. the Secretary erred in declining to require a permit system as a regulatory device;
3. no monitoring requirements were included in the final regulation; and
4. no specific tests were set forth as part of the requirements for medical examinations.

The first contention, suggesting that a no measurable exposure standard be used, presents the same difficulty in review as that discussed in the EI case. There, we pointed out that by extrapolating the testing on animal species to establish carcinogenicity in man, the Secretary was exercising a policy judgment rather than a purely factual determination.

Here, the Secretary stated that, while a safe level of exposure cannot be established by application of present

8. (Cont'd.)
mittee, whose recommendations had to be geared to cover all fourteen chemicals, permitted only closed vessel operation. The permanent standards prohibited open vessel operation. The Secretary contends that the revised definition of "closed vessels" formulated by the advisory committee and ultimately adopted in the permanent standard does permit certain open vessel operations involving MOCA. PMA questions this and asserts that had it been given the opportunity to meet the issues at a public hearing after being advised of the specific standard later adopted, it would have been able to develop the data to show that the unique properties of MOCA would permit safe operation in open vessels. We do not resolve that factual dispute here and merely point to it as an example of where compliance with the terms of the statute might have provided a regulation and standard more acceptable to all concerned.

Secretary has deferred implementation of monitoring requirements pending further scientific development of methods for doing so. Such a decision is a pragmatic one which will not be disturbed by the court.

Finally, OCAW attacks the provisions for medical examinations because they do not prescribe specific medical protocols and diagnostic tests to be given employees who work with the chemicals. The advisory committee suggested that employers should provide a comprehensive history and physical examination consisting of diagnostic tests and periodicity specific to the carcinogen and in no less detail than guidelines set forth by the Secretary of Labor after consultation with the Secretary of Health, Education and Welfare.

During the rule-making process, evidence was submitted which established that the various carcinogens acted on different bodily organs and that particular tests were required for specific chemicals. This evidence was another instance of the problems engendered by considering all of the substances as a group rather than on an individual basis.

The Secretary gave no reasons for ignoring this recommendation of the advisory committee, nor did he indicate, as he did in connection with monitoring devices, that further information was needed.

29 U.S.C. § 655(b)(7) provides, *inter alia:*

> "In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure."

In contrast to the standards adopted here, certain diagnostic tests are required by the regulations pertaining to asbestos workers, *see* 29 C.F.R. § 1910.93a(j)(2) & (3), and

some specificity is evident in the medical examination requirements for employees who are exposed to vinyl chloride, 39 Fed. Reg. 35897 (1974).

At oral argument, counsel for the Secretary posited that the existing broad standards could be interpreted to require any specific diagnostic tests which might be necessary. But this approach introduces an element of uncertainty not satisfactory to either employee or employer. It is important that the worker be assured of the benefits of medical procedures that are presently available and that industry be advised of what is expected of it. The regulations can be drafted with ample flexibility to take advantage of expanding medical knowledge in the field. Specific provisions need not discourage improvement or innovation in this critical area.

The failure of the Secretary to explain the lack of specific requirements making the medical examinations effective requires that we remand this aspect of the standards applicable to all of the chemicals.

In summary then, the regulations applicable to 4,4′ methylene bis (2-chloroaniline) (MOCA) will be remanded for the publication of a proposed standard, to be followed by the required procedures for allowance of comments and hearing. The regulations pertaining to laboratory usage of all the chemicals involved in these appeals are remanded so that appropriate notice may be issued to interested parties and opportunity provided for comment and hearing. The portion of the standards applicable to all of the chemicals referring to medical examinations will be remanded for further proceedings.

A True Copy:

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Clerk of the United States Court of Appeals for the Third Circuit.

(A.O.—U. S. Courts, International Printing Co., Phila., Pa.)

APPENDIX B

STATEMENT OF REASONS AND A REPRESENTATIVE CARCINOGEN STANDARD ISSUED BY SECRETARY OF LABOR JANUARY 29, 1974

The Statement of Reasons and Standards on Carcinogens issued by the Secretary of Labor, 29 C.F.R. §§ 1910.93*c-p*, 39 *Fed. Reg.* 3756 (January 29, 1974), are reprinted below. A representative standard has been selected, 29 C.F.R. § 1910.93*l*, since all fourteen standards are identical for the purposes of this petition.

TITLE 29—LABOR

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Carcinogens

Pursuant to section 6(b) and (c) of the Williams-Steiger Occupational Safety and Health Act of 1970 (29 U.S.C. 655) and Secretary of Labor's Order No. 12-71 (36 FR 8754), Part 1910 of Title 29, Code of Federal Regulations, is hereby amended in the manner set forth below, in order to provide standards dealing with the exposure of employees to certain substances that are known to cause cancer.

Background. On May 22, 1972, the Deputy Assistant Secretary of Labor for Occupational Safety and Health requested information from the Director of the National Institute for Occupational Safety and Health (NIOSH) on nine substances alleged to be carcinogens. As part of his effort to gain the best available scientific data, the Director published on July 6, 1972, at 37 FR 13285, a request for information concerning 15 substances. The data, arguments, and conclusions received by NIOSH were made available to the Occupational Safety and Health Administration.

On January 4, 1973, a petition for an emergency temporary standard from the Oil, Chemical, and At-

omic Workers Union (OCAW) and Health Research Group (HRG) was received by the Department of Labor. The petition contained relevant information on the danger of exposure to 10 carcinogens, and suggested regulations to prevent worker exposure to the substances.

On February 9, 1973, a notice was published in the FEDERAL REGISTER (38 FR 4037) of the receipt of the petition for issuance of an emergency temporary standard, and information was requested from interested persons on the issues involved. In response to the notice, more than 50 written comments were received.

An emergency temporary standard on carcinogens was promulgated on May 3, 1973, at 38 FR 10929. The standard concerned work practices and controls designed to protect employees from exposure to 14 carcinogenic substances.

A standard advisory committee on carcinogens was appointed and began its meetings on June 25, 1973. The members of the committee represented employers, employees, Federal and state agencies and professionals. The committee terminated its meetings on August 24, 1973, and submitted to the Assistant Secretary of Labor for Occupational Safety and Health its recommendations for a standard on certain carcinogens on August 27, 1973. The recommendations were published in the FEDERAL REGISTER on September 7, 1973 (38 FR 24375).

This rulemaking proceeding was commenced under section 6(b) and (c) of the Act, with the emergency temporary standard serving as a proposal as required by section 6(c)(3) of the Act. Notice of the proceeding was published in the FEDERAL REGISTER on July 16, 1973 (38 FR 18900). On July 27, 1973, a revision of the emergency temporary standard was published at 38 FR 20074, and an amended notice of rulemaking pro-

ceeding was published at 38 FR 22141, on August 16, 1973.

The notices invited interested persons to submit, prior to September 5, written comments, data and arguments concerning the proposals, and also provided for the presentation of oral testimony at a public hearing scheduled for September 11-14, 1973. Numerous written comments were received and about 36 parties testified at the hearing. The record of the hearing was initially held open until September 28, for additional comments. After the close and certification of the record by the administrative law judge, additional comments mailed on or before September 28 were received. On October 2 the judge reopened the record for the limited purpose of including these additional comments. On October 15, the judge closed the proceeding and forwarded the certified record to the Assistant Secretary of Labor for Occupational Safety and Health for final decision.

A final environmental impact statement on the proposed standard on carcinogens was filed with the Council on Environmental Quality on October 2, 1973, and copies were distributed to appropriate agencies. In a letter dated November 2, 1973, the Council pointed out alleged deficiencies in the statement filed. Pursuant to that letter, a supplement to the statement was sent to the Council on November 29, 1973, with a request for a waiver of the full, 30-day review period. By letter dated December 10, 1973, the Council advised that the request had been denied. Notice of the filing of the supplement was published by the Council on December 14, 1973 (38 FR 34488).

The following are the major issues raised in the record of this proceeding:

(1) *Selection of carcinogens.* Some participants in this proceeding have demanded to know the criteria

for the selection of the 14 substances for regulation. As the written submission of Uniroyal Chemical notes, thirteen compounds derive from Appendix A to the 1972 TLV pamphlet published by the American Conference of Government Industrial Hygienists (ACGIH). Alpha-Naphthylamine, which is not in the appendix, has been added because it has frequently been found, in industrial experience and in epidemiologic studies, together with beta-naphthylamine, and because experimental animal studies demonstrate its independent carcinogenicity, Dimethyl sulfate, which is in the appendix, is not included in the standards because it was concluded after consideration of the relevant literature that the documentation of its carcinogenicity was inadequate. The substances listed by ACGIH (except one) were selected in order to take advantage of the work and judgment of that group. Also, ten of the fourteen substances were proposed to the Occupational Safety and Health Administration (OSHA) for regulation by OCAW and HRG in their petition.

(2) *Documentation of carcinogenicity.* The National Institute for Occupational Safety and Health (NIOSH), as official scientific advisor to OSHA, submitted to OSHA fourteen hazard review documents; one for each of the substances included in the standards. Each hazard review document contains a summary and evaluation of information and data obtained by NIOSH, including experimental animal and epidemiologic data. All but one of the substances are considered by ACGIH to be carcinogenic in man and/or animals.

In promulgating these standards, OSHA has relied extensively but not exclusively, on the hazard review documents prepared by NIOSH. Some of the substances are recognized as human carcinogens by some employers participating in this proceeding. For in-

stance, although Young Aniline Works apparently takes issue with the studies which demonstrated Benzidine to be a human carcinogen, the Benzidine Task Force of the Synthetic Organic Chemical Manufacturers Association does not oppose OSHA considering benzidine as carcinogenic to humans.

The essence of the NIOSH hazard review documents follows.

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Ethyleneimine. The carcinogenic potential of ethyleneimine (EI) has been confirmed by a study conducted by Walpole in 1954 involving rats and one sponsored by the National Cancer Institute involving mice. In the first study, animals developed injection site sarcomas which the investigators attributed to the direct action of Ethyleneimine, and in the second study 80 percent of the animals developed tumors, including more than one-half with hepatomas (which the investigators stated had "malignant potentiality") and almost three-quarters with pulmonary tumors. Although high doses of EI were administered, the investigators stated there was no way to predict whether man would be more or less susceptible to tumor induction by EI.

The case for the carcinogenicity of EI, then, rests on the extrapolation to humans of the findings in two separate, controlled animal studies. This position is compatible with that of NIOSH concerning the prior demonstration of carcinogenicity in at least two animal studies.

A major question of occupational carcinogenesis relates to the extrapolation of results of animal experimentation to humans. The basis of numerous objections to the proposals is that, even assuming the validity of animal experiments, such do not furnish sufficient evidence that the substances involved are carcinogenic to humans. Extrapolation of results

obtained by animal experimentation is alleged to be vitiated by several considerations: (a) That certain cancers are specific only to some species; (b) that the conditions of animal experiments are out of proportion to, and not consistent with, conditions prevailing in industrial exposure; and (c) that no cancers have yet been detected in humans exposed to the substances. For those substances whose metabolism is understood, and is similar in both animals and man, the fact that they induce cancers in animals warrants the expectation that they will induce cancers in men. This applies to the substances which cause urinary bladder cancers in animals acting, not directly, but indirectly through the mediation of metabolites formed both in experimental animals and in exposed workers. This is also true of those substances which apparently require no metabolic alteration but attack a particular biologic system (e.g., respiratory tract, alimentary canal) which is similar in both animals and humans.

The objections raise the much broader issue of human exposure to a chemical which is only known to have caused cancers in experimental animals.

It is important to note that some opponents of the regulation of such chemicals do not advocate treating them as if they were harmless with respect to carcinogenic potential. Several employers, for instance insist that such substances must be treated with "care" or "respect," while also insisting that they call for significantly less protection than those substances known to be human carcinogens.

We think it improper to afford less protection to workers when exposed to substances found to be carcinogenic only in experimental animals. Once the carcinogenicity of a substance has been demonstrated in animal experiments, the practical regulatory alternatives are to consider them either non-carcinogenic or

carcinogenic to humans, until evidence to the contrary is produced. The first alternative would logically require, not relaxed controls on exposure, but exclusion from regulation. The other alternative logically leads to the treatment of a substance as if it was known to be carcinogenic in man.

We agree with the Director of NIOSH, and the report to the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General, U.S. Public Health Service, April 22, 1970, that the second alternative is the responsible and correct one. This decision accords with the work practices of some who object to the proposed regulation. For example, although the Pharmaceutical Manufacturers Association argues for the exclusion of research laboratories from the standard, it states as its ground the fact that employees in Pharmaceutical research are taught to work with all chemicals under the assumption that they are dangerous, unless it is specifically known that they are not.

(3) *The petition, zero tolerance, and permit system.* The petition of Oil, Chemical and Atomic Workers Union (OCAW) and Health Research Group (HRG) for an emergency temporary standard on ten substances proceeds on the assumption that any exposure to any amount of a carcinogenic substance must be prevented. Accordingly, it proposes a standard of zero tolerance permitting no exposure whatsoever. This objective would be accomplished by means of a permit system and frequent monitoring and reporting.

We agree with the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens that a safe level of human exposure to any of the 14 carcinogens cannot be established by application of present knowledge. But we are not prepared to

draw from this state of knowledge the conclusion that such levels do not exist. First, it is the professional opinion of many knowledgeable people that as yet undetermined safe levels of exposure possibly do exist. Also, a conclusion that safe levels do not exist seems questionable in view of other studies, some in the area of carcinogenicity which demonstrated that below a certain amount of a single or cumulative dosage, no detectable harm is caused, or if harm is caused, the extent of such harm will be of no practicable importance because the latency period prior to manifestation of harmful effects will be of greater duration than the normal lifespan of man. Secondly, no possible exposure to the carcinogens under any circumstances could only be guaranteed by a total ban on the manufacture, use (even for cancer research), and transportation of the substances. As long as the substances are used, exposure to some amounts may occur because of breakdown of equipment or human error. Accordingly, the intent of the standards is to reduce exposure of workers to any of the listed substances to the maximum extent practicable consistent with continued use.

Numerous objections have challenged the authority for, and the administrative feasibility of, the permit system proposed on July 16, 1973 (38 FR 18902). It is argued, for instance, that the Act requires the promulgation of general standards, in accordance with the procedures prescribed in section 6 of the Act, while the proposed permits would be tailored to particular users, and would be issued by a different procedure.

Another objection argues that a permit system, to be effective, would require authority to stop an operation involving a carcinogen by administrative action, in contravention of the statutory scheme which con-

templates judicial determinations resulting in the cessation of an operation.

With regard to feasibility, it is pointed out that a multitude of permits would be required, and that, therefore, the implementation of a permit system would require substantial resources and several years.

It has been made clear that there are numerous uses and processes involving carcinogens. It appears, for instance, that there are 800 to 1800 users of 4,4'-methylene bis(2-chloroaniline) alone. The investigations and evaluations of thousands of work situations involving a carcinogen, and the completion of the procedures, possibly including hearings, for the granting of the permits, would require many years and the diversion of substantial resources, even if available, from other serious occupational safety and health problems.

After considering the administrative and legal aspects of a permit system, as against those of general standards enforced by the use of the current enforcement tools of the Act, the decision has been made not to adopt a permit system.

The requirement in the adopted standards for employers to report the uses of carcinogens and the nature of operations involved, together with incidents of releases of carcinogens, will permit significant administrative surveillance.

(4) *Mixtures.* The proposal for this rulemaking proceeding, like the Emergency Temporary Standard, excludes from the scope of the standard mixtures containing less than specified percentages of the 14 listed substances. The specific figure as a cutoff point derives from the regulations of the Commonwealth of Pennsylvania and England, which also regulate exposure to carcinogens, and apparently have faced

the same administrative difficulties confronting OSHA. It is recognized that some of the carcinogens may be used in minute amounts with other substances, or may appear as unintended, undesired byproducts or contaminants of processes. Some of the substances are used in minute amounts in cancer research laboratories, and for medical purposes. The College of American Pathologists, for instance, points out that for years pathology laboratories and physicians have used benzidine and/or benzidine dihydrochloride for diagnostic purposes. The American Home Products Corporation calls attention to the use of beta-Propiolactone for the sterilization of vaccines and tissue grafts. Koppers, Inc., requests an exemption in some form for materials, such as coal tar and coal tar products, that contain trace amounts of some carcinogens as by-products or contamination of processes essential to our industrial society. It states that the application of the proposed standard to crude mixtures, such as coal tar and coal tar products, without any exemption, would have the effect of closing down large segments of industry, such as steelmaking, wood preserving, roofing, aluminum reduction, and possibly even power plants.

The adopted standards retain the proposed exclusion of solid or liquid mixtures containing less than 1 percent, by weight or volume, of eight of the carcinogens. Solid or liquid mixtures containing 4-Aminodiphenyl, Benzidine (and its salts), 4-Nitrobiphenyl, beta-Naphthylamine, bis-Chloromethyl ether and Methyl chloromethyl ether are excluded only if they contain less than 0.1 percent of those substances. Finally, an exclusion is provided in the destructive distillation of carbonaceous materials, for alpha-Naphthylamine and beta-Naphthylamine, which may occur in such processes.

The overall purpose of all the exclusions is to avoid substantial obstruction, if not stoppage, of the use of

many processes and products which are considered useful in industy and even in cancer research, and about which the record contains very little information. We do not know how many such products and processes there are, nor the availability of substitutes for all of the carcinogens involved, nor the effect of the other components of a mixture on the carcinogenic potentiality of the small amounts of the carcinogen involved. The exclusionary percentage for mixtures containing 4-Aminodiphenyl, Benzidine, 4-Nitrobiphenyl, beta-Naphthylamine, bis-Chloromethyl ether and Methyl chloromethyl ether has been lowered from 1 percent to 0.1 percent because these substances are known to be potent human carcinogens.

The exclusion for the destructive distillation of carbonaceous materials is for the purpose of avoiding the extreme consequences to the segments of the industry using vigorous thermal processes at a time when a separate standard-setting proceeding on coke oven emissions will afford the opportunity for a more in-depth consideration of this whole area (see 38 FR 26207). The exclusion of the mixtures rests, not on a finding that the mixtures are non-carcinogenic, but rather on a decision not to regulate them at this time, on the basis of the record of this proceeding.

(5) *Number of Standards Needed.* Another objection to the proposals is that the standard "lumps together" many different substances with different chemicals and physical properties, different physical states, different biological properties and different uses. There is merit in this objection. Accordingly, 14 standards are adopted, one for each substance listed in the proposal of July 16, 1973.

These standards recognize and provide for different uses and operations involving the regulated carcinogens. Ethyleneimine and beta-Propiolactone are

immediately corrosive, and provisions are made in the standards for these materials for deluge showers and eye wash fountains, located near places where exposures might be expected. Principally volatile materials will not be present long enough for routine washing or showering to have effect as a protective measure. Thus, a requirement to wash on each exit, and shower at the end of the day, would not offer any significant protection to employees working in areas where the volatile materials, Methyl chloromethyl ether, bis-Chloromethyl ether, Ethyleneimine and beta-Propiolactone, are present in a closed system or closed system transfer operation. Trace amounts that might be adsorbed onto exposed skin vaporize long before the employee would routinely wash or shower. Wash requirements are retained for these materials in isolated system operations because the closed confinement of glovebox gloves would inhibit vaporization if a leak should occur.

Special provisions are made for premix operations involving 4,4 Methylene-bis (2-chloroaniline) and liquid prepolymer. These premix solutions, frozen or otherwise, are packaged in such a manner and used only after the 4,4′-Methylene-bis(2-chloroaniline) and the prepolymer have started to react. No dust hazard exists and a vapor hazard is unlikely. For this reason, the standard requires only protective clothing such as smocks, coveralls, or long-sleeved shirts and pants, and gloves. This, we believe, will afford adequate protection for these workers.

On the other hand, some of the differences pointed out do not require different treatment. There are basically two strategies of control, regardless of the physical state of a carcinogen. One is to isolate the carcinogen and the other is to isolate the areas of possible exposure. In cases of isolated systems, the

physical state of the carcinogen may be disregarded for practical purposes. When a system is isolated and fully closed so that the substances cannot escape into the work environment, it does not matter if the substance in it is a solid, liquid, or gas. An isolated system achieved by engineering controls is the preferred approach and the basic approach adopted in the standards. That is, the preferred method of control is engineering control, such as by closed systems, mechanical seals, remote controls, and local exhaust ventilation. This approach most effectively isolates employees from potential contamination.

This is the reason for the ban on open vessel operations. Because of consideration of feasibility, special provisions are made for laboratory hoods and transfer point operations, and additional work practice requirements are made applicable to them.

When protection is afforded by means of personal protective equipment, it is thought best to require body coverage, regardless of the physical state of the substance and its path of travel into the body. The reason for such personal protection is that even if a substance is considered to do harm only when ingested or inhaled, it is prudent to provide protective garments to be discarded after use, so that a worker may not accidentally inhale or ingest contaminants adhering to his clothing or body. This precaution is reasonable, especially since the standards do not require full impervious air-supplied suits. OSHA agrees with the many comments that a full impervious air-supplied suit is cumbersome, while impervious garments with air-supplied hoods are adequate and more comfortable to the workers when used in accordance with the work practice provisions of these standards.

(6) *Research laboratories.* Numerous objections have been made to the proposal for identical treatment of

industrial use and laboratory use of the carcinogens. There are essentially three objections: (a) That laboratories use very small amounts of the substances; (b) that work is done by, or under the direction of, highly trained personnel; and (c) that, in the absence of an exemption or other special consideration, the standard as proposed would obstruct, and possibly even prevent much research including cancer research.

These objections are well-taken and special provisions are made applicable to laboratory activities. The provisions are derived from the Minimum Safety Guidelines for Research in Cancer (Part 1, For Research Involving Chemical Carcinogens), prepared in draft form by the Cancer Research Safety Committee of the National Cancer Institute. In addition, it is to be noted that the exclusion provisions for certain mixtures may, by themselves, make a whole standard inapplicable.

Personnel engaged in animal support activities must necessarily handle animals exposed in connection with experiments involving one or more of the carcinogens. Such support activities include the feeding of animals, cleaning of cages and the animal room, and caring for the animals, including weighing operations. Such close animal contact involves potential exposure both to a carcinogen and to metabolites of the carcinogen and therefore requires the more stringent controls for such personnel provided in the standards.

(7) *Signs and labels.* The controversy with regard to signs and labels centers on whether the word "cancer" should be used. We believe that a diluted form of warning will not suffice. We appreciate the concern of employers with the reactions of their employees and the users of their products. But we consider of paramount importance that a worker should be fully apprised and realize the possible risks in-

volved in his occupation. The use of the word "suspect" in the phrase "Cancer-Suspect" follows the revised Emergency Temporary Standard issued July 27, 1973. Coupled with the information and training requirement in the standard, it appears to provide the necessary warning to employees.

(8) *Information and training.* Employers are responsible for providing indoctrination and training to their employees on the nature of the carcinogenic hazards in the establishment, and the precautions to be used when working with or in the presence of the carcinogens. Information on the training and education to be provided to employees is specified in each of the standards for a carcinogenic agent.

(9) *Monitoring.* No provisions for specific techniques or instruments for environmental monitoring are contained in the standards adopted. OSHA has requested NIOSH to develop, on a priority basis, methods for determining qualitative and quantitative amounts of the carcinogens in the workplace.

(10) *Medical surveillance.* Medical surveillance by a physician is required in the standards prior to assignment, at yearly intervals thereafter and whenever known or possible exposure to a carcinogen has occurred. Medical surveillance is considered necessary because of the long latency period inherent in occupational carcinogenesis, since initiation of exposure and induction of cancer are not synchronous events.

(11) *Reports and records.* The standards require reports concerning the use of carcinogens, the number of employees in regulated areas, and incidents resulting in the release of a carcinogen in an area where employees may be potentially exposed. The standards also require records of medical examinations of employees. The reports and records are considered

necessary in order to monitor the effectiveness of the standards in protecting employees against occupational cancer and in order to obtain information, on a continuing basis, concerning the hazards found in the use of the carcinogens.

Accordingly, upon consideration of the whole record of this proceeding, 29 CFR Part 1910 is amended by revising § 1910.93c and by adding new §§ 1910.93d through 1910.93p, reading as follows:

§ 1910.93*l* *Ethyleneimine.*

(a) *Scope and application.* (1) This section applies to any area in which Ethyleneimine, Chemical Abstracts Service Registry Number 151564 is manufactured, processed, repackaged, released, handled, or stored, but shall not apply to transshipment in sealed containers, except for the labeling requirements under paragraphs (e)(2), (3), and (4) of this section.

(2) This section shall not apply to solid or liquid mixtures containing less than 1.0 percent by weight or volume of Ethyleneimine.

(b) *Definitions.* For the purposes of this section: (1) "Absolute filter" is one capable of retaining 99.97 percent of a mono disperse aerosol of 0.3 μm particles.

(2) "Authorized employee" means an employee whose duties require him to be in the regulated area and who has been specifically assigned by the employer.

(3) "Clean change room" means a room where employees put on clean clothing and/or protective equipment in an environment free of Ethyleneimine. The clean change room shall be contiguous to and have an entry from a shower room, where the shower room facilities are otherwise required in this section.

(4) "Closed system" means an operation involving Ethyleneimine where containment prevents the release

of Ethyleneimine into regulated areas, non-regulated areas, or the external environment.

(5) "Decontamination" means the inactivation of Ethyleneimine or its safe disposal.

(6) "Director" means the Director, National Institute for Occupational Safety and Health, or any person directed by him or the Secretary of Health, Education, and Welfare to act for the Director.

(7) "Disposal" means the safe removal of Ethyleneimine from the work environment.

(8) "Emergency" means an unforeseen circumstance or set of circumstances resulting in the release of Ethyleneimine which may result in exposure to or contact with Ethyleneimine.

(9) "External environment" means any environment external to regulated and nonregulated areas.

(10) "Isolated system" means a fully enclosed structure other than the vessel of containment of Ethyleneimine, which is impervious to the passage of Ethyleneimine, and which would prevent the entry of Ethyleneimine into regulated areas, nonregulated areas, or the external environment, should leakage or spillage from the vessel of containment occur.

(11) "Laboratory type hood" is a device enclosed on three sides and the top and bottom, designed and maintained so as to draw air inward at an average linear face velocity of 150 feet per minute with a minimum of 125 feet per minute; designed, constructed, and maintained in such a way that an operation involving Ethyleneimine within the hood does not require the insertion of any portion of any employees' body other than his hands and arms.

(12) "Nonregulated area" means any area under the control of the employer where entry and exit is neither restricted nor controlled.

(13) "Open-vessel system" means an operation involving Ethyleneimine in an open vessel, which is not in an isolated system, a laboratory type hood, nor in any other system affording equivalent protection against the entry of Ethyleneimine into regulated areas, nonregulated areas, or the external environment.

(14) "Protective clothing" means clothing designed to protect an employee against contact with or exposure to Ethyleneimine.

(15) "Regulated area" means an area where entry and exit is restricted and controlled.

(c) *Requirements for areas containing Ethyleneimine.* A regulated area shall be established by an employer where Ethyleneimine is manufactured, processed, used, repackaged, released, handled or stored. All such areas shall be controlled in accordance with the requirements for the following category or categories describing the operation involved: (1) *Isolated systems.* Employees working with Ethyleneimine within an isolated system, such as a "glove box" shall wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.

(2) *Closed system operation.* Within regulated areas where Ethyleneimine is stored in sealed containers or contained in a closed system, including piping systems, with any sample ports or openings closed while Ethyleneimine is contained within: Access shall be retricted to authorized employees only.

(3) *Open vessel system operations.* Open vessel system operations as defined in paragraph (b) (13) of this section are prohibited.

(4) *Transfer from a closed system, charging or discharging point operations, or otherwise opening a*

closed system. In operations involving "laboratory type hoods," or in locations where Ethyleneimine is contained in an otherwise "closed system," but is transferred, charged, or discharged into other normally closed containers, the provisions of this subparagraph shall apply. (i) Access shall be restricted to authorized employees only;

(ii) Each operation shall be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation. Exhaust air shall not be discharged to regulated areas, nonregulated areas or the external environment unless decontaminated. Clean makeup air shall be introduced in sufficient volume to maintain the correct operation of the local exhaust system.

(iii) Employees shall be provided with, and required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), and gloves prior to entering the regulated area.

(iv) Employees engaged in Ethyleneimine handling operations shall be provided with and required to wear and use a fuliface, supplied air respirator, of the continuous flow or pressure-demand type, in accordance with § 1910.134.

(v) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified, as required under paragraphs (e)(2), (3), and (4) of this section.

(vi) Drinking fountains are prohibited in the regulated area.

(5) *Maintenance and decontamination activities.* In cleanup of leaks or spills, maintenance or repair operations on contaminated systems or equipment, where direct contact with Ethyleneimine could result, each authorized employee entering that area shall: (i) Be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood in accordance with § 1910.134.

(ii) Be decontaminated before removing the protective garments and hood;

(iii) Be required to shower upon removing the protective garments and hood.

(6) *Laboratory activities.* The requirements of this subparagraph shall apply to research and quality control activities involving the use of Ethyleneimine. (i) Mechanical pipetting aids shall be used for all pipetting procedures.

(ii) Experiments, procedures and equipment which could produce aerosols shall be confined to laboratory-type hoods or glove boxes.

(iii) Surfaces on which Ethyleneimine is handled shall be protected from contamination.

(iv) Contaminated wastes and animal carcasses shall be collected in impervious containers which are closed and decontaminated prior to removal from the work area. Such wastes and carcasses shall be incinerated in such a manner that no carcinogenic products are released.

(v) All other forms of Ethyleneimine shall be inactivated prior to disposal.

(vi) Laboratory vacuum systems shall be protected with high-efficiency scrubbers.

(vii) Employees engaged in animal support activities shall be *(a)* provided with, and required to wear, a complete protective clothing change, clean each day, including coveralls or pants and shirt, foot covers, head covers, gloves, and appropriate respiratory protective equipment or devices; and

(b) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified as required under paragraphs (e)(2), (3), and (4) of this section.

(c) Required to shower after the last exit of the day.

(viii) Employees, other than those engaged only in animal support activities, each day shall be *(a)* provided with and required to wear a clean change of appropriate laboratory clothing, such as a solid front gown, surgical scrub suit, or fully buttoned laboratory coat.

(b) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The containers shall be identified as required under paragraphs (e)(2), (3), and (4) of this section.

(c) Required to wash hands, forearms, face and neck upon each exit from the regulated area close to the point of exit, and before engaging in other activities.

(ix) Air pressure in laboratory areas and animal rooms where Ethyleneimine is handled and bioassay

studies are performed shall be negative in relation to the pressure in surrounding areas. Exhaust air shall not be discharged to regulated areas, nonregulated areas or the external environment unless decontaminated.

(x) There shall be no connection between regulated areas and any other areas through the ventilation system.

(xi) A current inventory of Ethylenemine shall be maintained.

(xii) Ventilated apparatus, such as laboratory type hoods, shall be tested at least semi-annually or immediately after ventilation modification or maintenance operations, by personnel fully qualified to certify correct containment and operation.

(d) *General regulated area requirements*—(1) *Employee identification.* A daily roster of employees entering regulated areas shall be established and maintained. The rosters or a summary of the rosters, shall be retained for a period of 20 years. The rosters and/or summaries shall be provided upon request to authorized representatives of the Assistant Secretary and the Director. In the event that the employer ceases business without a successor, rosters shall be forwarded by registered mail to the Director.

(2) *Emergencies.* In an emergency, immediate measures including, but not limited to, the requirements of subdivisions (i), (ii), (iii), (iv), and (v) of this subparagraph shall be implemented. (i) The potentially affected area shall be evacuated as soon as the emergency has been determined.

(ii) Hazardous conditions created by the emergency shall be eliminated and the potentially affected area shall be decontaminated prior to the resumption of normal operations.

(iii) Special medical surveillance by a physician shall be instituted within 24 hours for employees present in the potentially affected area at the time of the emergency. A report of the medical surveillance and any treatment shall be included in the incident report, in accordance with paragraph (f)(2) of this section.

(iv) Where an employee has a known contact with Ethyleneimine, such employee shall be required to shower as soon as possible, unless contraindicated by physical injuries.

(v) An incident report on the emergency shall be reported as provided in paragraph (f)(2) of this section.

(vi) Emergency deluge showers and eyewash fountains supplied with running potable water shall be located near, within sight of, and on the same level with locations where a direct exposure of Ethyleneimine would be most likely as a result of equipment failure, or improper work practice.

(3) *Hygiene facilities and practices.* (i) Storage or consumption of food, storage or use of containers of beverages, storage or application of cosmetics, smoking, storage of smoking materials, tobacco products or other products for chewing, or the chewing of such products, are prohibited in regulated areas.

(ii) Where employees wear protective clothing and equipment clean change rooms shall be provided, in accordance with § 1910.141(e), for the number of such employees required to change clothes.

(iii) Where toilets are in regulated areas, such toilets shall be in a separate room.

(iv) Where employees are required by this section to wash, washing facilities shall be provided in accordance with § 1910.141(d)(1) and (2)(ii) through (vii).

(v) Where employees are required by this section to shower, shower facilities shall be provided in accordance with § 1910.141(d)(3).

(4) *Contamination control.* (i) Regulated areas, except for outdoor systems, shall be maintained under pressure negative with respect to nonregulated areas. Local exhaust ventilation may be used to satisfy this requirement. Clean makeup air in equal volume shall replace air removed.

(ii) Any equipment, material, or other item taken into or removed from a regulated area shall be done so in a manner that does not cause contamination in nonregulated areas or the external environment.

(iii) Decontamination procedures shall be established and implemented to remove Ethyleneimine from the surfaces of materials, equipment and the decontamination facility.

(e) *Signs, information and training*—(1) *Signs.* (i) Entrances to regulated areas shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT
AUTHORIZED PERSONNEL ONLY

(ii) Entrances to regulated areas containing operations covered in paragraph (c)(5) of this section shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT EXPOSED IN THIS AREA IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD REQUIRED AT ALL TIMES, AUTHORIZED PERSONNEL ONLY

(iii) Appropriate signs and instructions shall be posted at the entrance to, and exit from, regulated areas, informing employees of the procedures that must be followed in entering and leaving a regulated area.

(2) *Container contents identification.* (1) Containers of Ethyleneimine and containers required under

paragraphs (c)(4)(v) and (c)(6)(vii) (*b*), and (c) (6) (viii)(*b*) of this section which are accessible only to, and handled only by, authorized employees, or by other employees trained in accordance with subparagraph (5) of this paragraph, may have contents identification limited to a generic or proprietary name, or other proprietary identification, of the carcinogen and percent.

(ii) Containers of Ethyleneimine and containers required under paragraphs (c)(4)(v), (c)(6)(vii)(*b*), and (c)(6)(viii)(*b*) of this section which are accessible to, or handled by employees other than authorized employees or employees trained in accordance with subparagraph 5 of this paragraph shall have contents identification which includes the full chemical name and Chemical Abstracts Service Registry number as listed in paragraph (a)(1) of this section.

(iii) Containers shall have the warning words "CANCER-SUSPECT AGENT" displayed immediately under or adjacent to the contents identification.

(iv) Containers which have Ethyleneimine contents with corrosive or irritating properties shall have label statements warning of such hazards, noting, if appropriate, particularly sensitive or affected portions of the body.

(3) *Lettering.* Lettering on signs and instructions required by subparagraph (1) of this paragraph shall be a minimum letter height of 2 inches. Labels on containers required under this section shall not be less than ½ the size of the largest lettering on the package, and not less than 8 point type in any instance: *Provided,* That no such required lettering need be more than 1 inch in height.

(4) *Prohibited statements.* No statement shall appear on or near any required sign, label, or instruction which contradicts or detracts from the effect of any required warning, information or instruction.

(5) *Training and indoctrination.* (i) Each employee prior to being authorized to enter a regulated area, shall receive a training and indoctrination program including, but not necessarily limited to: *(a)* The nature of the carcinogenic hazards of Ethyleneimine, including local and systemic toxicity;

(b) The specific nature of the operation involving Ethyleneimine which could result in exposure;

(c) The purpose for and application of the medical surveillance program, including as appropriate, methods of self-examination;

(d) The purpose for and application of decontamination practices and purposes;

(e) The purpose for and significance of emergency practices and procedures;

(f) The employee's specific role in emergency procedures;

(g) Specific information to aid the employee in recognition and evaluation of conditions and situations which may result in the release of Ethyleneimine;

(h) The purpose for and application of specific first aid procedures and practices;

(i) A review of this section at the employee's first training and indoctrination program and annually thereafter.

(ii) Specific emergency procedures shall be prescribed, and posted, and employees shall be familiarized with their terms, and rehearsed in their application.

(iii) All materials relating to the program shall be provided upon request to authorized representatives of the Assistant Secretary and the Director.

(f) *Reports*—(1) *Operations.* Not later than March 1, 1974, the information required in subdivisions (i), (ii), (iii), and (iv) of this subparagraph shall be reported in writing to the nearest OSHA Area Director. Any changes in such information shall be similarly reported in writing within 15 calendar days of such change. (i) A brief description and in-plant location of the area(s) regulated and the address of each regulated area;

(ii) The name(s) and other identifying information as to the presence of Ethyleneimine in each regulated area;

(iii) The number of employees in each regulated area, during normal operations including maintenance activities and

(iv) The manner in which Ethyleneimine is present in each regulated area; e.g. whether it is manufactured, processed, used, repackaged, released, stored, or otherwise handled.

(2) *Incidents.* Incidents which result in the release of Ethyleneimine into any area where employees may be potentially exposed shall be reported in accordance with this subparagraph. (i) A report of the occurrence of the incident and the facts obtainable at that time including a report on any medical treatment of affected employees shall be made within 24 hours to the nearest OSHA Area Director.

(ii) A written report shall be filed with the nearest OSHA Area Director within 15 calendar days therafter and shall include: *(a)* A specification of the amount of material released, the amount of time involved, and an explanation of the procedure used in determining this figure;

(b) A description of the area involved, and the extent of known and possible employee exposure and area contamination, and

(c) A report of any medical treatment of affected employees, and any medical surveillance program implemented; and

(d) An analysis of the circumstances of the incident, and measures taken or to be taken, with specific completion dates, to avoid further similar releases.

(g) ***Medical surveillance.*** At no cost to the employee, a program of medical surveillance shall be established and implemented for employees considered for assignment to enter regulated areas, and for authorized employees. (1) ***Examination.*** (i) Before an employee is assigned to enter a regulated area, a preassignment physical examination by a physician shall be provided. The examination shall include the personal history of the employee, family and occupational background, including genetic and environmental factors.

(ii) Authorized employees shall be provided periodic physical examinations, not less often than annually, following the preassignment examination.

(iii) In all physical examinations, the examining physician shall consider whether there exist conditions of increased risk, including reduced immunological competence, those undergoing treatment with steroids or cytotoxic agents, pregnancy and cigarette smoking.

(2) *Records.* (1) Employers of employees examined pursuant to this paragraph shall cause to be maintained complete and accurate records of all such medical examinations. Records shall be maintained for the duration of the employee's employment. Upon termination of the employee's employment, including retirement or death, or in the event that the employer ceases business without a successor, records, or notarized true copies thereof, shall be forwarded by registered mail to the Director.

(ii) Records required by this paragraph shall be provided upon request to authorized representatives of the Assistant Secretary or the Director; and upon request of an employee or former employee, to a physician designated by the employee or to a new employer.

(iii) Any physician who conducts a medical examination required by this paragraph shall furnish to the employer a statement of the employee's suitability for employment in the specific exposure.

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APPENDIX C

STATUTE INVOLVED

Occupational Safety and Health Act
of 1970, 29 U.S.C. §655(b)

* * *

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

* * *

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate,

such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health, Education, and Welfare, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health, Education, and Welfare, may by rule promulgated pursuant to section 553 of title 5, United States Code, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

* * *

APPENDIX D

UNITED STATES COURT OF APPEALS FOR FOR THE THIRD CIRCUIT

No. 74-1129
No. 74-1149
No. 74-1268

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, *et al.*,

Petitioners in No. 74-1129

v.

PETER J. BRENNAN, Secretary, Department of Labor, and JOHN H. STENDER, Assistant Secretary of Labor for Occupational Safety and Health,

Respondents

OIL, CHEMICAL & ATOMIC WORKERS INTERNATIONAL UNION, AFL-CIO and HEALTH RESEARCH GROUP,

Petitioners in No. 74-1149

v.

PETER J. BRENNAN, Secretary United States Department of Labor, *et al.*,

Respondents

POLYURETHANE MANUFACTURERS ASSOCIATION,

Petitioner in No. 74-1268

v.

DEPARTMENT OF LABOR, PETER J. BRENNAN, Secretary Department of Labor, etc., *et al.*,

Respondents

ON PETITION FOR REVIEW OF ACTION OF THE ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH

Present: HASTIE, GIBBONS and WEIS, *Circuit Judges*

JUDGMENT

These causes came on to be heard on the record from the Assistant Secretary of Labor for Occupational Safety and Health, and were argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the proceedings be, and the same are hereby remanded insofar as the standards relating to medical examinations, applicable to all chemicals, are concerned; and it is further here ordered and adjudged by the Court that the regulations applicable to 4,4' methylene bis (2-chloroaniline) (MOCA) be, and the same are hereby vacated, and the cause be, and the same is hereby remanded for the publication of a proposed standard, to be followed by the required procedures for allowance of comments and hearing; and it is further here ordered and adjudged by this Court that to the extent that the standards in question relate to research laboratories, the said standards be, and the same are hereby vacated, and the cause be, and the same is hereby remanded to OSHA for further proceedings, all in accordance with the opinion of this Court.

ATTEST:

/s/ Thomas P. Quinn
Clerk

December 17, 1974